STERILE COMPOUNDING SELF-ASSESSMENT

THE CONTENTS OF THIS SELF-ASSESSMENT MAY BE USED AS A GUIDE BY PHARMACIES APPLYING FOR A STERILE COMPOUNDING LICENSE TO DETERMINE COMPLIANCE WITH ALL AREAS OF THE REGULATIONS GOVERNING STERILE COMPOUNDING

COMPLETE TEXT CAN BE FOUND IN CALIFORNIA CODE OF REGULATIONS ARTICLE 8, SECTION 1751

Designations: C means Compliant, NC means Non-Compliant

CCR 1751: COMPOUNDING AREA FOR PARENTERAL SOLUTIONS

C	NC	
___	___	The pharmacy must have a designated area for the preparation of sterile products for dispensing.
___	___	The Clean room and workstation have walls, ceilings and floors made of non-porous cleanable surfaces.
___	___	The area is well ventilated.
___	___	The laminar air flow and clean room equipment are certified annually by a qualified and knowledgeable technician familiar with such methods and processes.
___	___	Items related to compounding parenteral solutions within the compounding area are not stored in corrugated cardboard boxes, moreover they are stored in such a way as to maintain the integrity of an aseptic environment.
___	___	There is a sink with hot and cold running water.
___	___	There is a refrigerator and/or freezer of sufficient capacity to meet the storage requirements for all material requiring refrigeration.

CCR 1751.1: LAMINAR FLOW BIOLOGICAL SAFETY CABINET

___	___	Pharmacies preparing parenteral cytotoxic agents must have a biological safety cabinet (vertical laminar air flow hood).
___	___	The biological safety cabinet must be certified by a qualified technician familiar with the methods and procedures for certifying laminar air flow hoods and clean room environments.
___	___	Certification records must be retained for 3 years.

CCR 1751.2: LABELING REQUIREMENTS

In addition to existing labeling requirements, the following information must be included on all labels:

___	___	Telephone number of the pharmacy.
___	___	Name and concentrations of all ingredients contained in the parenteral

product including primary solution.

___ ___ Instructions for storage and handling.

___ ___ All cytotoxic agents must bear a special label which states "Chemotherapy-Dispose of Properly".

CCR 1751.3: RECORD KEEPING REQUIRMENTS

___ ___ Records are available on the premises or are readily accessible. There is a record for each patient being treated with parenteral therapy.

___ ___ Records detail the furnishing of all prescriptions and medical supplies.

Information relevant to the patient's parenteral therapy shall include, but not limited to:

___ ___ Patient'sname, age, sex, address, and body weight.

___ ___ Primary diagnosis related to the need for prescribed therapy; secondary diagnosis if available.

___ ___ Summary of most recent hospitalization and/or previous history.

___ ___ Medication history, including current diet/medication regimen and drug/food allergies.

___ ___ Progress notes documenting contact with the patient or physician relative to parenteral therapy.

___ ___ Laboratory data relevant to parenteral therapy.

CCR 1751.4: PROTECTIVE CLOTHING

___ ___ Gloves and gowns are worn when preparing cytotoxic agents.

CCR 1751.5: TRAINING OF STAFF, PATIENT AND CAREGIVER

___ ___ Consultation shall be available to the patient and/or primary caregiver and include proper use of parenterals and related supplies.

___ ___ The pharmacist-in-charge shall be responsible to ensure all pharmacy personnel have training and demonstrated competencies in the safe handling and compounding of parenteral products including cytotoxic agents.

___ ___ Records of training and demonstrated competence shall be available for each individual and retained for 3 years beyond the date of employment.

___ ___ The pharmacist-in-charge shall be responsible to insure the continuing competence of pharmacy personnel engaged in compounding parenteral solutions.

CCR 1751.6: DISPOSAL OF WASTE MATERIAL

___ ___ Written policies and procedures exist for the disposal of infectious materials and/or material containing cytotoxic residues.

___ ___ Procedures must include cleanup of spills and be in conformance with local health jurisdiction.

___ ___ The pharmacy ensures the return of waste material or communicates

the proper destruction of such materials to the caregiver.

CCR 1751.7: QUALITY ASSURANCE

___ ___ There is an on-going quality assurance program that monitors personnel performance, equipment, and facilities.

___ ___ The end product shall be examined on a sampling basis as determined by the pharmacist-in-charge to assure that the product meets required specifications.

The Quality Assurance program shall include:

___ ___ Cleaning and sanitization of the parenteral medication preparation area.

___ ___ Written documentation that the end product has been tested on a sampling basis for microbial contamination and steps taken in the event that testing for contamination proves positive.

___ ___ If manufacturing of parenteral products is performed using nonsterile chemicals, extensive end product testing must be documented prior to the release of the product from quarantine and must include testing for sterility and pyrogens.

___ ___ Storage of compounded parenteral products

___ ___ Periodic documentation of refrigerator temperature.

___ ___ Steps to be taken in the event of a drug recall.

___ ___ Written justification of the chosen expiration date for compounded parenteral products.

CCR 1751.8: POLICIES AND PROCEDURES

___ ___ Written polices and procedures are present and include:

___ ___ Compounding and labeling of intravenous admixtures.

___ ___ Administration of intravenous therapy.

___ ___ Equipment and supplies

___ ___ Training of staff, patient and caregiver.

___ ___ Procedures for handling cytotoxic agents.

___ ___ Quality Assurance program.

___ ___ Record keeping requirements.

CCR 1751.9: REFERENCE MATERIALS

___ ___ Current reference materials are located in or immediately available to the pharmacy.

References shall include information on:

___ ___ Drugs and chemicals used in parenteral therapy services.

___ ___ All parenteral therapy manufacturing, dispensing, distributing, and counseling services provided.

OTHER CONSIDERATIONS:

CCR TITLE 24, SECTION 490a.7 COMPOUNDING AREA

___ ___ The clean room and workstations must be in accordance with Federal Standard 209(b) and meet standards for class 100 HEPA (high efficiency Particulate air) filtered air such as a laminar air flow hood or clean room.

___ ___ The pharmacy is arranged in such a manner that the laminar air flow hood is located in an area which is exposed to minimal traffic flow and is separate from any area used for bulk storage of items not related to the compounding of parenteral solutions.

___ ___ There must be sufficient space, well separated from the laminar air flow hood area, for the storage of bulk materials, equipment and wast materials.

___ ___ A sink with hot and cold running water must be within the parenteral solutions compounding area or adjacent to it.

CCR TITLE 24, SECTION 505.11

___ ___ The pharmacy area designated for preparation of sterile products for dispensing shall be ventilated in a manner not interfering with laminar air flow.

CCR TITLE 24, SECTION 505.11.1 – LAMINAR FLOW BIOLOGICAL SAFETY CABINET

___ ___ There is present of a Class II type A or Class II Type B vertical laminar air flow hood with bag-in-bag out design for preparing cytotoxic agents.

___ ___ Pharmacy must ensure that contaminated air plenums that are under positive air pressure are leak tight.